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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,513	08/16/2001	Keith G. Copeland	97,008-W	5062

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BEX, PATRICIA K

ART UNIT	PAPER NUMBER
1743	3

DATE MAILED: 04/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/931,513	COPELAND ET AL.
	Examiner P. Kathryn Bex	Art Unit 1743

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 August 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 72-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 72-98 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The addition of claims 72-98 in Paper no. 2 and the cancellation of claims 1-71, in Paper no. 3 is acknowledged and has been entered into the record.

Specification

2. The abstract of the disclosure is objected to because it contains legal phraseology, such as "means" and "said," which should be avoided. Correction is required. See MPEP § 608.01(b).
3. The specification is missing disclosure of Figure 34 in the "Brief Description of Drawings" section, see page 12. Correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 72-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72, last line, "said first solution *zone*" lacks antecedent basis.

Claim 74, line 1, "the step of applying reagent" lacks antecedent basis. Examiner believes this should be changed to --a step of applying reagent--. Similar deficiency was found in claim 96.

Claim 81, line 1, "reagent" lacks antecedent basis. What reagent is Applicant referring to?

Claim 87, last line, "said aqueous solution *zone*" lacks antecedent basis.

Claim 98, is essentially a "whereby" clause. It has been held that the functional "whereby" statement does not define any structure and accordingly can not serve to distinguish. *In re Mason*, 114 USPQ 127, 44 CCPA 937 (1957).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 72, 74-75, 77-78, 87-91, 96-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Saunders (USP 4,483,882).

Saunders anticipates the method substantially as claimed. Saunders teaches a method for preparing blood spreads for microscopic examination comprising the steps of; contacting a blood sample on a slide with an agent producing a cross-linked matrix in the plasma, then immersing the blood film in a non-polar (water-immiscible) solvent to control surface tension and prevent evaporation. Lastly, performing chemical reactions by diffusing chemical reagents across the interface between the non-polar solvent and the blood. Wherein the non-polar solvent is mixed into the first solution using a spinner (see Examples I-II and claim 1).

8. Claims 72, 77, 79-80, 84-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazza *et al* (USP 4,815,978).

Mazza *et al* anticipate the method substantially as claimed. Mazza *et al* teach clinical analysis methods of liquid biological samples. The method comprising the steps of; dispensing a reagent tablet in cuvette 24, then dispensing an aqueous diluent 52 into the cuvette. Next, adding

biological sample into the cuvette from sample dispenser 80. Then, adding a second reagent from a dispensing station 54 into the cuvette (column 7, lines 2-9). Lastly, an air jet mixing apparatus 15a provides for thorough remixing of the cuvette contents following the addition of the second reagent at station 54. The air jet J is directed an acute angle at the junction of the liquid surface in the cuvette such that the air jet hits the meniscus at this junction. A vortex is created which produces a through mixing of the contents of the cuvette. This mixing is such that even a reagent which is immiscible in the diluent becomes totally suspended with the diluent and the reaction between the reagent and the sample is more complete and rapidly achieved (column 8, lines 38-47, Figs.1-2, 4-5, 9-10).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 73, 79-85, 92-93, 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunders (USP 4,483,882) in view of Gibbs *et al* (USP 3,854,703).

Saunders discloses an automatic method and apparatus for preparing blood smears for microscopic examination. However, Saunders fails to recite the step of stirring via at least one gas stream to an area on a surface of the second solution. Gibbs *et al* disclose a device which may be used in combination with devices to treat specimen material to prepare it for subsequent microscopic examination. The device of Gibbs *et al* disclose a specimen support tape 2 which is drawn through the device and a vortex mixer with outlets 14, or jet needles 22, for mixing a reagent and diluents with a specimen material before examination (column 3, lines 10-25, Figs. 2, 4). Air is supplied from the chamber and issues from an opposing outlet pair 14 between the biological mixture's edge and the edge of the tape, such that the pool is pushed back towards the middle of the tape (column 3, lines 1-7, Fig. 3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Saunders with a step of stirring via a gas stream, as taught by Gibbs *et al*, in order to conveniently mix very small samples and reduce the possibility of cross-contamination (column 1, lines 21-39).

Allowable Subject Matter

12. Claims 76, 86 and 94 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
13. The following is a statement of reasons for the indication of allowable subject matter: the instant claims are drawn to an automated slide staining method. While numerous slide staining methods exist, none of the prior art teaches or suggest providing a step of applying a second solution to an impact zone, wherein the impact zone is between the biological sample and end of

the support medium and wherein the step of applying reagent includes applying reagent to an area between the impact zone and the edge of the biological sample.

Conclusion

14. No claims allowed.
15. The prior art made of record and not relied upon which is considered pertinent to applicant's disclose are Kanamori *et al*, Heidt *et al*, Melnyk, Bogen, Wootton *et al*, Louder *et al*, and Binnings *et al*. They are cited of interest in that they show various methods for automated biological reactions on slides.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex
P. Kathryn Bex
Patent Examiner
AU 1743
April 9, 2002

Jill Warden
Jill Warden
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